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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/202,455	12/15/98	YAMAGUCHI K	FJN-070

HM22/0619

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EXAMINER	
HAMUD,F	
ART UNIT	**PAPER NUMBER**
1647	16

DATE MAILED: 06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary

Application No.	Applicant(s)
09/202,455	Yamaguchi et al
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 11, 2001*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *65-67, 69, 72-82, and 84-90* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *65-67, 69, 72-82, and 84-90* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 15

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. Receipt of Applicant's arguments and amendments filed in Paper No.14, 03/29/01 is acknowledged.

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 85 has been renumbered 84.

3. Claims 65, 69, 73, 77, 78, 81, 87 and 89 have been amended and claims 68, 70, 71 and 83 have been canceled in Paper No.14, filed on March 29, 2001. Thus claims 65-67, 69, 73-82 and 84-90 are under consideration by the Examiner.

4. The following previous objections and rejections are withdrawn in light of Applicants amendments filed in Paper No.14, 03/29/01:

(I) The rejection of claims 69, 72, 77-81 and 84-90 made under 35 U.S.C. §102(e), as being anticipated by Boyle.

(II) The rejection of claims 79, 82-87 made under 35 U.S.C. §102(b), as being anticipated by Anderson.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Applicant's arguments filed in Paper No.14, 03/29/01, have been fully considered but were deemed persuasive in part. The issues remaining are restated below.

Claim objections

7. Claims 69, 77, 80, 81, 82, 84-86 and 88 are objected to because of the following informalities:

Claims 69, 77, 80, 81, 82, 84-86 and 88 are objected to, because there should be a colon after SEQ ID NO instead of a period, i.e SEQ ID NO:1 instead of SEQ ID NO.1.

Claim Rejections - 35 USC § 112

8. The rejection of claims 65-67, 72-79, 81, 87, 89 and 90, under U.S.C. § 112, first paragraph is maintained for reasons of record set forth in the office action mailed on 11/07/00 in Paper NO.13, pages 3-9.

Applicants argue that an analysis of enablement requires a determination of whether the disclosure, when filed contained sufficient information regarding the subject matter of the claims to enable one skilled in the pertinent art to make and use the claimed invention and the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. Applicants also argue that instant specification not only discloses the protein and nucleic acid sequences of both mouse and protein homologs of OCIF binding protein, but further provides detailed guidance and specific protocols for isolating additional proteins and nucleic acids based on homology. Applicants further submit that given the redundancy of the genetic code, it is standard practice to the USPTO to provide to inventors of such sequences reasonable protection from others who can alter their sequences to avoid infringement by

providing inventors with protection for highly similar sequences which are capable of hybridizing to their sequences under stringent hybridization conditions and which also retain the functionality of their sequences. Applicants also argue that they provide detailed protocols of making and using their claimed invention in the Examples by providing basic protocols for testing the binding capacity of the OCIF-binding protein.

These arguments have been fully considered but are not deemed persuasive. As was set forth in previous office action instant specification is enabling for an isolated mouse osteoclastogensis inhibitory (OCIF) binding protein comprising the amino acid sequence set forth in SEQ ID NO:1 or 16 and an isolated human OCIF binding protein comprising the amino acid sequence set forth in SEQ ID NO:11 or 17, said polypeptide encoded by a polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:2 or 15, SEQ ID NO:12 or 19 respectively, wherein said polypeptide comprises a molecular weight of approximately 40,000 Daltons by SDS-PAGE, and wherein said polypeptide promotes osteoclast differentiation and maturation, a fragment of the polypeptide of SEQ ID NO:1 comprising amino acid residues 72-316 or 76-316, and a method of recombinantly making said polypeptides, however, it is not enabling for "all" possible mouse or human purified osteoclastogensis inhibitory (OCIF) binding proteins comprising a molecular weight of approximately 40,000 Daltons by SDS-PAGE which promote osteoclast differentiation and maturation, as claimed in amended claim 65. The amendment to claim 65 that the claimed protein comprise a molecular weight of approximately 40,000 Daltons by SDS-PAGE does not provide sufficient characteristics for the claimed protein. Having a molecular weight of approximately 40,000 Daltons by SDS-PAGE does not ensure that

the claimed protein would necessarily promote osteoclast differentiation and maturation, and the claim has no other characteristics for the claimed protein. Instant specification is only enabling for a protein that comprises the amino acid sequence set forth in SEQ ID NO:1, 11, 16 or 17, wherein said protein binds to osteoclastogenesis inhibitory factor and promotes osteoclast differentiation and maturation. With respect to claim 77, Applicants do not disclose a purified and isolated polypeptide encoded by a nucleic acid sequence which hybridizes to the complement of SEQ ID NO:2, 12, 15, 18, or 19 wherein said polypeptide has the ability to bind OCIF. One skilled in the art would not be able to predict if a protein encoded by a nucleic acid sequence which hybridizes to the complement of SEQ ID NO:2, 12, 15, 18, or 19 would retain the ability to bind to OCIF. Although the Examiner agrees with Applicant's argument that Inventors should get reasonable protection to avoid infringement for their claimed sequences, however one cannot merely predict protein function from amino acid sequence information neither can one predict if nucleic acids that hybridize under stringent conditions would encode a protein that retains the desired function. Because it is not routine to determine the function of proteins based on sequence data alone, and because one of skill could not predict which of the sequences that hybridize under stringent conditions to the complement of SEQ ID NO:2, 12, 15, 18, or 19 would encode an active OCIF binding protein, one wishing to make the invention would have to synthesize all the sequence that hybridize under stringent conditions to the complement of SEQ ID NO:2, 12, 15, 18, or 19, and subsequently determine which of these sequences encoded a functional protein. One might argue that it would not be undue experimentation to express and assay each cDNA individually and thereby determine empirically which ones encoded functional polypeptides.

However, as set forth in In re Fisher, 166 USPQ 18 (CCPA 1970), compliance with 35 USC 112, first paragraph requires:

> that scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement varies inversely with degree of unpredictability of factors involved.

It is agreed that Applicants have provided assays and protocols for testing the binding capacity of the OCIF-binding protein, however, one of skill in the art would have to perform undue experimentation to synthesize all the sequences that hybridize under stringent conditions to the complement of SEQ ID NO:2, 12, 15, 18 or 19 and characterize them to figure out which ones bind to OCIF.

Thus Applicants are only enabled for an isolated mouse osteoclastogensis inhibitory (OCIF) binding protein comprising the amino acid sequence set forth in SEQ ID NO:1 or 16, and an isolated human OCIF binding protein comprising the amino acid sequence set forth in SEQ ID NO:11 or 17, said polypeptide encoded by a polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:2, 15, 12 or 19, respectively.

Claim Rejections - 35 U.S.C. § 102

9. The rejections of claims 69, 72-78, 80-81, 88 and 90 under 35 U.S.C. 102(e) as being anticipated by Anderson et al (US Patent 6,017,729) is maintained for reasons of record set forth in the office action mailed on 11/07/00 in Paper NO.13, pages 10-11.

Conclusion

10. No claim is allowable.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Mondays and Thursdays and every other Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
June 11, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud